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112/750,927	12/13/76	ROTHSCHILD	FIRST NAMED INVENTOR	112/750,927	ATTORNEY DOCKET NO.
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DVORAK EXAMINER

23012	ART UNIT	PAPER NUMBER
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01/08/98

DATE MAILED:

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

<b>Office Action Summary</b>	Application No. 08/753,929	Applicant(s) Rothschild et al
	Examiner Linda C.M. Dvorak	Group Art Unit 3302

Responsive to communication(s) filed on Dec 5, 1997

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle* 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claim

Claim(s) 1-37 is/are pending in the application

Of the above, claim(s) 6-8, 11, 12, 19-23, 25, 26, 32-34, 36, and 37 is/are withdrawn from consideration

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 1-5, 9, 10, 13-18, 24, 27-31, and 35 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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## DETAILED ACTION

### *Election/Restriction*

Applicant's election without traverse of species I, figures 3A-3D in Paper No. 5 is acknowledged. Claims 1-5, 9, 10, 13-18, 24, 27-31, and 35 will be examined by the examiner. Claims 6-8, 11, 12, 19-23, 25, 26, 32-34, and 36-37 are herein withdrawn from consideration as being drawn to non-elected species.

### *Specification*

The disclosure is objected to because of the following informalities: Page 3, line 12, "to" should read --too--. Page 8, line 9, --of-- should be inserted after "view". Page 9, line 10, "a" should be deleted. Page 15, line 6, should "sheer" read --sheet--?

Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

Claims 10, 24, and 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "is extended below the malleoli posterior above tendon and curved centered" is indefinite because the use of the verb "extended" to describe how the brace is intended to

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interact with the user's leg implies that the leg ( or malleoli) is an integral component of the instant invention. The human body and its parts are not considered statutory subject matter and cannot be claimed. The claims should be modified so that the intended function of the recited structure can be accomplished by the structure itself without implying that the body is in any way a component of the invention. For instance, the "extended" in the aforementioned phrase could be modified to read --adapted to extend-- or --positioned within the posterior of the positive mold so as to extend ...when the brace is properly positioned during use" . Additionally, in the aforementioned phrase, the meaning of "above tendon and curved centered" is unclear and requires clarification.

*Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 13, 15, 16, and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Mason et al [4289122].

Mason et al discloses a method of forming a foot orthosis comprising the steps of forming a positive mold of the extremity; positioning a thermoformable plastic material around

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predetermined locations on the mold [8]; wrapping a thermoformable sheet around the mold and the thermoplastic material; and vacuum sealing the thermoplastic sheet around the mold so that the thermoplastic sheet and thermoplastic material combine together. Note particularly figures 6-10.

Regarding claim 13, see col. 3, lines 37+.

Regarding claim 15, note orthosis 1 with reinforcing area 8.

Regarding claim 16, the two pieces are integrally formed.

Regarding claim 28, the area "8" is considered to be a "predetermined reinforcement location" as broadly as claimed.

Claims 15, 16, 27 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Mason et al [4938777].

Mason et al discloses a foot orthosis comprising a rigid support structure formed from a thermoplastic material [10] wherein the support is reinforced in predetermined areas with additional thermoplastic material [14].

Regarding claim 16, note col.4 , line 33.

Regarding claim 27, the mold is considered to be "modified" as broadly as claimed.

Regarding claim 28, the area "14" is considered to be a "predetermined reinforcement location" as broadly as claimed.

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*Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2, 3, 17, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mason et al ['122].

Mason et al does not specifically recite the composition of his thermoplastic material; however, absent a statement of criticality, the recited material would have been an obvious design choice as the selection of a known material based upon its suitability for the intended use is a design consideration within the skill of the art. In re Leshin, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

Claims 9 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mason et al as applied to claim 1 above, and further in view of Rogers [3916886].

Mason et al discloses the instant invention as discussed, *supra*, but does not disclose the specifics of the reinforcing strip as claimed. Rodgers discloses the desirability of a reinforced area with the approximate dimensions claimed for better supporting the posterior of a foot orthosis. It would have been obvious to one having ordinary skill in the art at the time of applicant's invention

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to make the reinforced area of the dimensions claimed in light of the desirability of an analogously dimensioned reinforcement in the orthosis of Rodgers.

Claims 17, 18, 29, 30, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mason et al ['777].

Mason et al does not specifically recite the composition of his thermoplastic material; however, absent a statement of criticality, the recited material would have been an obvious design choice as the selection of a known material based upon its suitability for the intended use is a design consideration within the skill of the art. In re Leshin, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

Regarding claim 31, Mason et al teaches reinforcement in the area over the medial malleoli and the recitation of such a reinforcement being 3/16" is viewed as an obvious design consideration not patentably distinct over the reinforcement of Mason et al.

#### *Allowable Subject Matter*

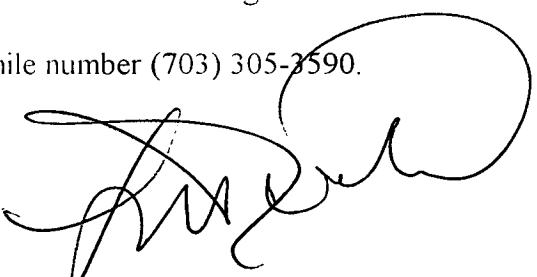
Claims 4 and 5 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Claim 10 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112 set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

*Conclusion*

Any inquiry concerning this communication should be directed to Linda C. M. Dvorak at telephone number (703) 308-0994. In addition, facsimile transmissions concerning this application should be directed to Linda C. M. Dvorak at facsimile number (703) 305-3590.



LINDA C. M. DVORAK  
EXAMINER  
ART UNIT 3302

LCM Dvorak  
January 5, 1998